Meeting Minutes, Open Session, Drug Utilization Review Board September 10, 2020		
Drug Utilization Review Board *Due to COVID-19, this meeting was held virtually.	**DUR Board Members:** Moneeshindra Mittal, MD, Chair (Absent) James Backes, PharmD, Interim Chair Jennifer Clair, MD Katie Burenheide Foster, PharmD, MS, BCPS, FCCM Kristen Powell, PharmD LaTonyua Rice, PharmD, BCGP Arthur Snow, MD Serena Stutzman, APRN Roger Unruh DO **KDHE/DHCF/Contractor Staff:** Annette Grant, RPh. Victor Nguyen, PharmD Carol Arace, Sr. Admin. **DXC Technology Staff/KEPRO Staff** Karen Kluczykowski, RPh Kathy Kaesewurm, RN, BSN Harry Vu, PharmD **MCO Staff:** Jan Mueller, RPh, UnitedHealthcare Community Plan Alan Carter, PharmD, Aetna Better Health of Kansas Angie Yoo, PharmD, Sunflower State Health Plan	**Public Attendees**: Mckenzie Stratton, Sarepta; Daren Grothe, Dave Miley, Teva; Donna Osterlund, Sanofi; Gina Heinen, Mary Shefchyk, Novo Nordisk; Janie Huff, Tricida; Todd Dickerson, Jazz Pharma; Jeff Knappen, Sparks; Jim Baumann, Phil King, Pfizer; Karen Floeder, Chelsea Leroue, Biohaven Pharmaceuticals; Kim Walter, Johnson & Johnson; Kristi Kemp, Allergan; Melissa Basil, Seth Bernstein, Josh Bishop, AbbVie; Lucy Hernandez, Horizon Therapeutics; Marc Parker, Sunovion; Rhonda Clark, Gilbert Rodriguez, Indivior; Ricki Roberson, Merck; Tami Sova, Biogen; Chrissy Faulkner, Tanner Bain, Scott Donald, KEPRO; Ahmad Nessar, Britt Ward, Chris Guenther, Julie Cibaise, Laura Conner, Genentech; Andi Stratton, Eric Cox, Novartis; Audrey Rattan, Kellie Vazzana, Shelley Thompson, Alkermes; Brett Mccave, Immune Therapeutics; Britton Zuccarelli, Salina Regional Health Center; Bryan Moore, Roche; Doug Wood, Viiv Healthcare; Erin Hohman, Janssen; Kate Kulesher, Sandoz; Raquel Jordan, AstraZeneca

TOPIC	DISCUSSION	DECISION
I. Call to Order	Dr. Backes called the meeting to order at 11:05 a.m. and proceeded with a DUR Board member roll call.	
Announcements and Introductions	The meeting operator informed everyone of her role and the process for the meeting. Dr. Backes asked the State for any announcements. The State announced that by email response a majority of the Board members are fine to move the meetings to every third Wednesday of January, April, July, and October. This new rotation will start January 2021. Also, the State mentioned that the Medication Assisted Treatment drugs are on the agenda, but it is not to limit access, but to address a federal law that had an unforeseen negative impact to the State. This proposal will probably be temporary and would help the State to navigate through this situation.	
II. Old Business **A. Review and Approval of July 8, 2020 Meeting Minutes**	**Board Discussion:** Dr. Backes asked if there were any clarifications or comments to the July 8, 2020 minutes.	Dr. Burenheide-Foster sustained due to not being at the July meeting. Dr. Powell moved to approve the minutes. Dr. Unruh seconded the motion. The motion was approved, unanimously.
III. New Business **A. Mental Health Medication Advisory Committee (MHMAC)** **1. Antidepressant Medications – Safe Use for All Ages**	**Background:** At the August 2020 MHMAC meeting, the committee approved the revised criteria for use of Antidepressant Medications – Safe Use for All Ages prior authorization (PA). This revision included adding dosing limits as part of the PA criteria language to coincide with the dosing table previously added. There were minor updates to the dosing table and key. Step Therapy was added for Aplenzin®, Forfivo® XL, Viibryd®, Fetzima®, and Trintellix. **Public Comment: None**	Dr. Snow moved to approve. Dr. Burenheide-Foster seconded motion. The motion was approved unanimously.

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	Board Discussion: Dr. Powell asked for clarification for the added dosing table. If a provider with a pediatric patient wants to start a patient on a non-approved medication, will that medication require a prior authorization? The State showed the table key and said that not approved means insufficient evidence available or pediatric dosing was not reviewed and not recommended. The clinical PA form has a written peer-to-peer section for xxxxx. If the plan psychiatrist does not agree with the written response, a verbal peer-to-peer review will be required. Discussion and clarification that provider's with exemption status would not be allowed to bypass the dosing limits without an approved prior authorization (PA). Grandfathering approval for criteria changes is allowed for other situations.	
2. Antipsychotic Medications - Safe Use for All Ages	**Background:** At the August 2020 MHMAC meeting, the committee revised the criteria for use of Antipsychotic Medications – Safe Use for All Ages PA to include an update to diagnosis section for children less than six years old and an update to the renewal criteria. **Public Comment:** None. **Board Discussion:** Dr. Powell asked if there is an ICD-10 code for this added indication. The State said that they try to limit Point-of-Sale diagnosis requirements. For this younger age group this would process as the current set up, but this is a small increase in access but with caution. Dr. Powell says that the PA reviewers typically deny without the specific code. The State will need to discuss this part further. Dr. Backes asked the MCO pharmacists if they had seen or have any concerns with this process. Dr. Carter from Aetna said that he did not see any patterns of concern.	Serena Stutzman, APRN motioned to approve. Dr. Unruh seconded motion. The motion was approved unanimously.

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B. Revised Prior Authorization (PA) Criteria 1. **Minimum Requirements Prior Authorization**	**Background:** This revision includes additions or edits for the following agents: (Fintepla®, Evenity®) **Public Comment:** None. **Board Discussion:** None.	Dr. Powell motioned to approve. Dr. Snow seconded motion. The motion was approved unanimously.
2. **Opioid Dependence Agents**	**Background:** This revision adds current Non-Covered Outpatient Drugs for Medication Assisted Treatment to the PA list, requires prescribers of Opioid Use Disorder drugs to be DATA 2000 Waivered, and requires all preferred PDL drugs to be tried prior to non-preferred PDL drugs. **Public Comment:** None. **Board Discussion:** The State explained that the 2018 SUPPORT Act required that all MAT drugs be covered but did not make this requirement fall under the current Medicaid Drug Program federal rules. This meant that drugs not currently meeting the definition of Covered Outpatient Drug by CMS definition would need to be built into the claims system logic and that the State would also not be able to collect drug rebates for these drugs. This PA will address those concerns. There is legislation currently being proposed to fix this situation and is expected to pass prior to the 10/01/2020 effective date. Dr. Backes summarized and confirmed with the State, the overall reason of bringing this to the Board. Dr. Powell asked how other states are handling this issue. The State said that some are doing nothing, and some are trying to make all the accommodations. For Kansas, we are taking a phased approach. We are directing drug management to be in compliance with the law, with as little system work as possible, and have a phase two process in place, if this doesn't get reversed/fixed. Dr. Powell confirmed that the State is pretty much open access to this treatment already and that the limitations are for specific NDCs not currently covered. The State	Dr. Rice moved to approve. Serena Stutzman, APRN seconded the motion. The motion was approved unanimously.

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	confirmed that all the current drugs are covered and there are many NDCs for each drug, currently covered. There are additional NDCs that we would not cover unless all other NDCs in the system are not available on the market. This also helps management if a new drug of the same benefit comes out and is extremely expensive without additional benefit. The State could choose to limit its access through these standard processes.	
3. **Spinal Muscular Atrophy (SMA) Agents**	**Background:** This revision includes addition of Evrysdi™ (risdiplam) to the drug list and PA criteria. **Public Comment:** Ahmad Nessar, the Medical Affairs Executive Director for Genentech, explained that there were two studies that showed that beta-2 agonists [albuterol] have a positive effect on SMN protein levels. Genentech excluded these patients to be able to confirm patient benefit from their drug only. Also, in regard to Spinraza® and Zolgensma®, the European guidelines [consensus Statements] do not recommend concurrent use. Additionally, regarding symptoms, clinicians and experts agree that the early the treatment is initiated the better overall benefit for the patients treated. Dr. Backes asked about the rarity of the disease and Dr. Nessar said that the current prevalence is about 10,000 patients in the United States. **Board Discussion:** Dr. Backes asked about the albuterol part of the criteria. The State said that part came from the SUNFISH study, where patients on albuterol were excluded from the study. Dr. Backes asked about the number of Medicaid patients. The State did not have the current number or predicted increase, but the State said that there were five patients from what was last known. The State believed that with this being an oral solution, parents are more likely to seek this regimen versus the intrathecal route for Spinraza®. Access should be greater.	Dr. Clair moved to approve. Dr. Burenheide-Foster seconded the motion. The motion was approved unanimously.

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C. **New Prior Authorization (PA) Criteria** 1. **Tecartus™ (brexucabtagene autoleucel)**	**Background:** Tecartus is a CAR T-cell therapy for adult patients with relapsed or refractory mantle cell lymphoma. It is used following disease progression while on or after other treatment. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and to ensure appropriate use. **Public Comment:** None. **Board Discussion:** None	Serena Stutzman, APRN moved to approve. Dr. Powell seconded the motion. The motion was approved unanimously.
D. **New Preferred Drug List (PDL) Classes** **1. COPD Agents- Triple Therapy**: (Breztri Aerosphere™, Trelegy Ellipta)	**Background:** At the September 9, 2020 PDL meeting, a new PDL class called COPD Agents – Triple Therapy was approved. This class currently includes the agents Breztri Aerosphere™ and Trelegy Ellipta. **Public Comment:** None **Board Discussion:** Dr. Powell asked about whether agents are preferred or non-preferred and if the PDL Committee or the DUR Board determines that. The State said that the function of the PDL Committee is to determine if the drugs within the proposed PDL class are clinically equivalent and if the class can be added to the master PDL. Since the DUR Board is the final approval pharmacy committees, the DUR Board reviews the PDL Committee PDL class approvals. After that, any new drug to an existing PDL class is determined by the PDL Committee. Preferred and non-preferred PDL status determination is done by the State.	Dr. Powell moved to approve. Dr. Burenheide-Foster seconded the motion. The motion was approved unanimously.

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2. Colony Stimulating Factors – Filgrastim Products: (Granix®, Neupogen®, Nivestym™, Zarxio®)	**Background:** At the September 9, 2020 PDL meeting, a new PDL class Colony Stimulating Factors – Filgrastim Products was approved. This class currently includes the agents Granix®, Neupogen®, Nivestym™, and Zarxio®. **Public Comment:** None **Board Discussion:** None.	Dr. Snow moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
3. Colony Stimulating Factors – Pegfilgrastim Products: (Fulphila®, Neulasta®, Neulasta® Onpro®, Udenyca®, Ziextenzo®)	**Background:** At the September 9, 2020 PDL meeting, a new PDL class Colony Stimulating Factors – Pegfilgrastim Products was approved. This class currently includes the agents Fulphila®, Neulasta®, Neulasta® Onpro®, Udenyca®, Ziextenzo®. **Public Comment:** None **Board Discussion:** Dr. Backes mentioned that the prices for these biosimilars do not show the significant generic savings that we are used to seeing. The State mentioned that we have been seeing more price increases to the generic products lately.	Dr. Snow moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
4. Migraine – Acute Treatment Agents: (Nurtec™ ODT, Reyvow™, Ubrelvy™)	**Background:** At the September 9, 2020 PDL meeting, a new PDL class Migraine – Acute Treatment Agents was approved. This class currently includes the agents Nurtec™ ODT, Reyvow™, Ubrelvy™. **Public Comment:** Josh Bishop, clinical pharmacist from AbbVie spoke to Ubrelvy™, regarding access for the patient population that does not respond to triptans which are the first line treatments for acute migraine treatment. That the patient should only be required to try one triptan before approval for these	Serena Stutzman, APRN, moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

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	agents, and that requiring a neurologist provider type may limit patient access. Additional Ubrelvy™ drug features were also mentioned. **Board Discussion:** Dr. Backes asked the State to pull up the PA criteria that Mr. Bishop was referring to. The decision to go with a trial of two triptans came from the guidelines. Each triptan is trial is only required for two weeks' time. The State required a specialist out of concern for and to rule out underlying clinical issues. Dr. Backes mentioned concern for possible lack of specialists, known issues with triptans, and the newness (unknowns) of the new agents. Dr. Backes requested comment from the prescriber members of the Board. Dr. Clair said that based upon her experience, she was not aware of any concern about lack of neurologists. Serena Stutzman, APRN, said that she is not aware of an issue with access to neurologists. If patients do not respond to the second triptan, that would be a time to send them to a neurologist to make sure that something wasn't missed earlier in the diagnosis.	
5. Opioid Dependence Agents: (Bunavail, Naltrexone Tablets, Probuphine®, Sublocade™, Suboxone®, Subutex, Vivitrol®, Zubsolv®)	**Background:** At the September 9, 2020 PDL meeting, a new PDL class Opioid Dependence Agents was approved. This class currently includes the agents Bunavail, Naltrexone Tablets, Probuphine®, Sublocade™, Suboxone®, Subutex, Vivitrol®, Zubsolv®. **Public Comment:** Shelley Thompson, a medical science liaison with Alkermes represented Vivitrol and mentioned her appreciation of the open access for this product. **Board Discussion:** A brief review of the points mentioned during the clinical PA review were made by the State. Additionally, mention that the majority of the agents listed would be made preferred. Subutex will most likely have non-preferred PDL status because it has been known to be highly diverted. Patients currently on any of these agents will be grandfathered. Grandfathering means that if a patient has 80% or better adherence rate, for maintenance drugs, they can continue taking the drug that they are	Dr. Clair moved to approve. Serena Stutzman, APRN, seconded the motion. The motion was approved unanimously.

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	currently on. Dr. Powell mentioned diversion concerns between dose forms. Dr. Backes asked for clarification of the role of the PDL Committee versus the DUR Board. The State explained the separate and joint functions for each committee regarding the State PDL. Dr. Backes requested that the utilization for this drug class be ran in six months versus the usual annual PDL class review. Cost impact should be looked at because of the wide price differences between the agents. The State agreed.	
IV. Open Public Comment	Ricky Robertson from Merck asked what the months are for the 2021 DUR Board meetings. The State responded that they will stay the same: January, April, July, and October. **Board Discussion:** Dr. Powell asked about what change would happen if the SUPPORT Act was amended as anticipated. The State said that they had not thought about the continuance or removing of that PDL class as a result of the issue being resolved. Many states do have these agents on their PDLs. The clinical PA was really a change/non-change update. All current drugs in our system will still be allowed and any non-rebate eligible drugs would still not be allowed, unless there are no other rebate eligible options on the market.	
V. Adjourn	The meeting adjourned at 1:05 p.m.	Serena Stutzman, APRN moved to adjourn. Dr. Rice seconded the motion. The motion to adjourn was approved unanimously.

The next DUR Board meeting is scheduled for October 14, 2020.

All approved PA criteria are posted to the KDHE website- http://www.kdheks.gov/hcf/pharmacy/pa criteria.htm